GPhA
Generic Pharmaceutical Association

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August 8, 2002

Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane
Room 1061 – HFA-305
Rockville, MD 20852

Re: Docket No. 02N-0204
Bar Code Label Requirements for Human Drug Products

Dear Sir or Madam:

On behalf of the Generic Pharmaceutical Association (GPhA), I would like to thank Secretary Thompson for his efforts to reduce medication errors and for providing an opportunity for industry comment on bar code labeling of human drugs and biologics.

GPhA represents 98% of generic drug manufacturers whose drugs are dispensed for 45% of all prescriptions filled in the United States, representing less than 10% of total US drug expenditures. GPhA is now the united voice of the generic drug industry and is completely committed to patient health and safety, and strongly supports any measure aimed at improving these.

Medication errors comprise a significant portion of medical errors according to the Institute of Medicine report *To Err Is Human: Building a Safer Health System*. In June 2001, the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) published recommendations to address this problem including the use of standardized bar code labeling of all human drug products down to the unit dose level and each level of packaging. The recommendations also included specification of attributes to be contained in such a standardized code.

At the public meeting on this subject convened by FDA July 26, 2002, testimony from hospital groups, caregivers, and others clearly indicated their conviction that standardized bar coding would indeed minimize medication errors, especially in hospital settings, and most supported the NCC MERP recommendations in spirit if not to the letter. Also conveyed at the public meeting was the assertion that bar coding is but a single element in an overall "system" that would need to be implemented to assure comprehensive management of the issue.

GPhA also supports the NCC MERP recommendations with regard to prescription medicines. (Other stakeholders are in a better position to comment on non-prescription drugs and medical devices.) But we agree with the view that the bar coding of medicines by manufacturers is but a single point to consider. The capital expenditures to implement this technology are a

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consideration not only for manufacturers but for hospitals and pharmacies as well. Several individuals at the July 26 public meeting stated that a mere 1% of hospitals were currently equipped in some fashion with bar code scanners. Careful implementation of a bar code system, such that the coding would deliver as robust an impact on the problem as possible would mean equipping and training nurses at the point of care, pharmacists dispensing the medicines, and technicians to maintain the equipment. It would also mean careful and seamless integration with information systems governing patient records, and supply tracking and billing systems. And to be truly useful, seamless, and transparent, all these things-the code and the information content and data formats, need to be standardized across manufacturers of the medicines and providers of the encoding and scanning technologies, and the databases into which the encoded information would be read.

A further consideration is the choice of technology. While some endorsed specific coding technologies at the public meeting, it was clear that most felt flexibility in coding and scanning technology were of paramount importance along with the ability of the system to accommodate future needs in a sensible way. Indeed, some emphasized that the authentication technology itself should not be standardized, i.e., not necessarily bar codes, and that any technology that reads a standardized data set and format is the true goal.

At this time, given the complexity of the issue, and the number and types of affected stakeholders, GPhA will not endorse a specific technology at this time. However, we do fully support unit dose coding for prescription medications as far the technology will allow and as far as it will have a legitimate impact on reduction of medication errors. Given the capital investment by pharmaceutical manufacturers, hospitals and others needed to deploy and maintain this technology, and the needs of end-users to efficiently and consistently utilize it, careful thought and planning need to occur to ensure that whatever system is chosen, it provides the information truly necessary to reduce point-of-care medication errors. GPhA supports allowing for flexibility for pharmaceutical manufacturers and users with regard to technology.

Given the complexities of the issue and the needs of all the affected constituencies, GPhA recommends formation of a task force. The group would be responsible for determining the information content of any code, the data format and code placement and a timetable for planning and implementation phases. Some of the participants of this task force should include the end-users of the technology, pharmacists, drug manufacturers, FDA, and bar code/labeling technology companies. GPhA stands ready to participate in such a task force and extends an offer to assist in its formation and operation.

Thank you for the chance to provide these comments. Please do not hesitate to contact me with any questions

Steve Bende, Ph.D.

Vice President
Science, Professional and Regulatory Affairs

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